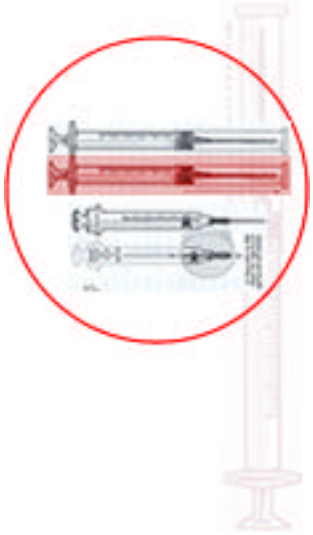
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.

SAFER MEDICAL DEVICE IMPLEMENTATION IN HEALTH CARE FACILITIES

SHARING LESSONS LEARNED

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.

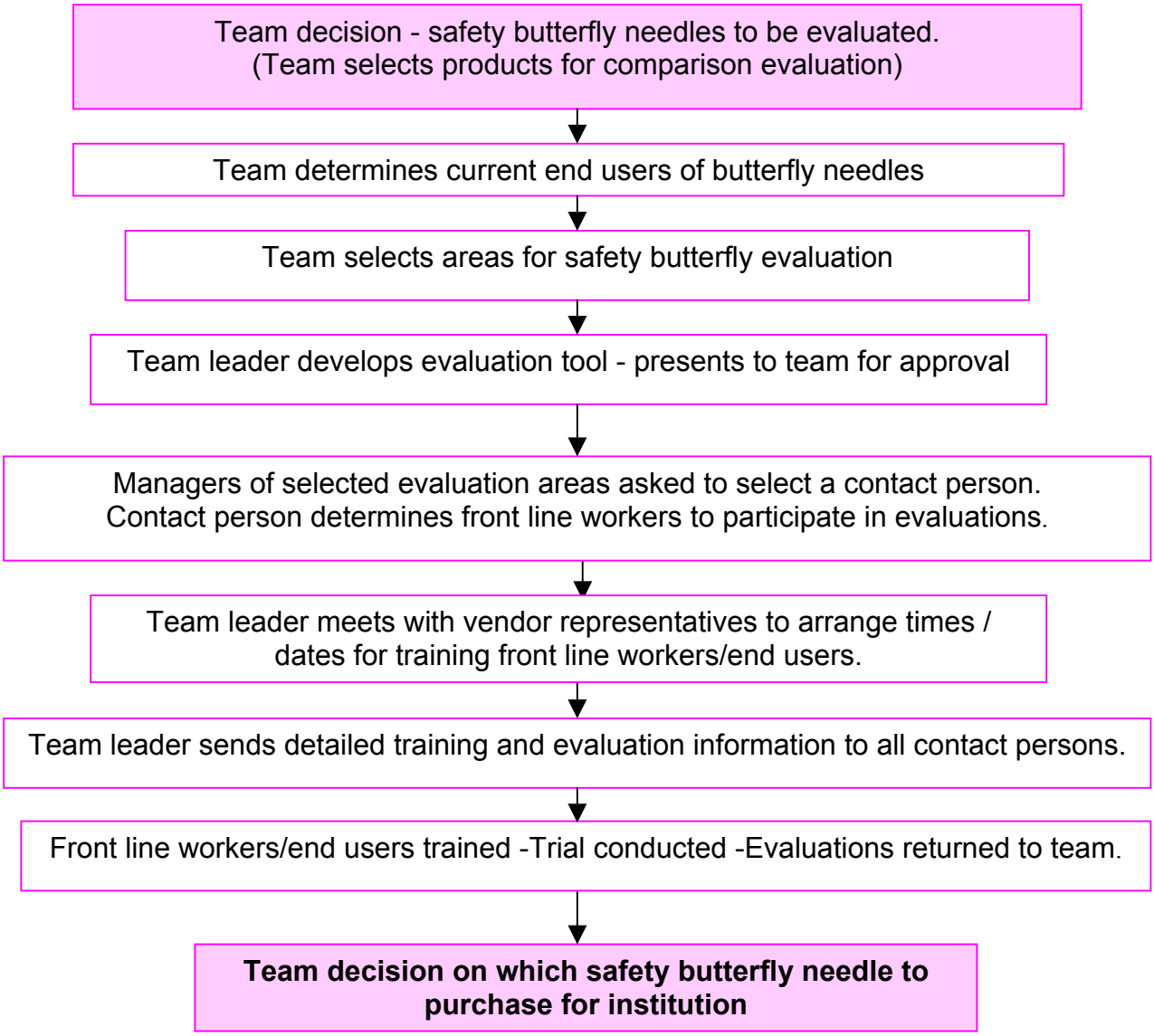


Phase 4: Evaluate Safer Medical Device(s)

Facility Description:
Large private, not-for-profit, academic medical center that includes over 950 hospital beds, twelve family health centers, two ambulatory surgical centers, a research institute and an education foundation. Over 2,000,000 outpatient visits and more that 50,000 hospital admissions each year. Facility employs over 1000 physicians representing approximately 120 specialties and subspecialties, approximately 3,000 nurses and a wide range of technical and support staff. Total number of employees is approximately 13,000.

Evaluation Process

Our institution has conducted multiple evaluations on a variety of sharps safety devices. All evaluations were conducted in a similar manner. The following information about butterfly needle (winged needle) evaluations demonstrates the process.



Identify the end users
Once a product(s) had been selected for evaluation the team determined the location of end users for the product. End users were identified by the following mechanisms:

- Knowledge of team members
- Storeroom data (if available)
- E-mail questionnaires of department heads and managers

Selection of evaluation locations
Once end users were identified the team selected areas for product evaluation. For most safety *needle* products evaluation units were selected based on the following criteria:

- High volume use
- Areas with patient populations known to have difficult venous access i.e., chemotherapy patients
- Pediatric areas

Development of evaluation tool
The key to a valuable evaluation is obtaining useful information from the front line workers/end users. Ideally an evaluation tool should:

- Address all the issues related to product use
- Be simple to fill out
- Be short in length

Meeting these criteria is not easy. Too simplistic a form may not provide enough information. An overly complex form may confuse users or prevent them from taking time to complete the form. In earlier evaluations we used evaluation tools from **The Training for Development of Innovative Control Technologies (TDICT) Project** located at:
http://www.tdict.org/criteria.html

TDICT forms are short and simple to use. However, we discovered that we could not differentiate subtle product differences using these tools. We decided to develop more extensive questionnaires. The team leader wrote questions developed from general reading and knowledge of product evaluation. All evaluation tools were reviewed and approved by the Sharps Injury Prevention Team.

See attached sample evaluation tool for butterfly needles. **Addendum #1**

Contact persons
Due to the size and complexity of the institution it was necessary to establish contact persons for each unit/area involved in a product evaluation. In some cases they were team members. If an area was selected that had no representation on the team then the manager was asked to provide a contact person. Contacts were responsible for selecting end users (both experienced and novice practitioners), arranging training sessions, distributing product and collecting evaluations.

Product training

Product vendors were required to supply training. Training sessions were to be conducted at times convenient to the end users and arranged with the area contact person. Vendors were aware of competitors involved in the evaluation.

Product supply

Vendors supplied all products for the evaluation free of charge. The team determined amounts for each user. Users could ask for additional product if they desired.

Evaluation time frame

Time frames were established for evaluations. Some areas took days, others weeks to complete the evaluation based on usage. For example, phlebotomy completed a butterfly needle trial in a few days, while nursing units took several weeks.

Product evaluation guideline

A product evaluation guideline was sent to contact persons and vendors involved in the evaluation. Each evaluation followed a similar format. See example - **Addendum #2**.

Results

All evaluations were returned to the team leader. The team leader tallied the evaluation results. For each question on the evaluation tool a mean score was calculated.

For example

- 44 evaluations returned
- Evaluator circled a response to each question on a scale of 1 through 5
- Mean score was calculated for each question

Question scale	1	2	3	4	5	N/A*	No response*	
Number of responses to the question	27	1	2	0	8	3	3	Total # of responses on scale 1-5 = 38
Total number of points for each response	27	2	6	0	40	0	0	Total # of points = 75

Mean score for question

75 points divided by 38 responses = 1.97

* No points if question response was not applicable (N/A) or no response given to the question.

A summary was presented to the team along with pricing information obtained from purchasing. The team made final recommendations to the Safety Committee for product implementation. See example results - **Addendum # 3**

Difficulties encountered

- End users would stop using the test product after one or two times if they did not immediately like it. This would occur more frequently with products requiring significant changes in technique. End users had to be cajoled and encouraged to use up all of their test product (get past the learning curve) before they completed the evaluation form. Vendor representatives were encouraged to provide frequent visits for troubleshooting and providing additional training.
- Contact persons had difficulty getting evaluation forms completed and returned. Asking vendors to participate in collecting evaluation forms worked well. Several vendors supplied candy to the end user in return for a completed form.

Lessons Learned

- E-mail questionnaires were very useful in identifying non-traditional areas that might use safety products. E-mail is a useful tool when working in a large institution with multiple facilities.
- Be sure to involve politically influential areas in the evaluation.
- Have a list of names of all end users in evaluations. This allows tracking of process and returned evaluation forms.
- Allow several months for large evaluations. It takes a lot of time to coordinate an evaluation and tally up results. The process will always take longer than anticipated.
- Use e-mail to get status reports from contact persons.
- Ask for weekly updates. Allow time to correct any problems in the process.
- Put the vendors to work. They expect to work hard to get their products into a large institution. Let them do a lot of the "leg work" for the team.
- Use team members as contact persons as much as possible. Team members are motivated and understand the process. When using non-team members as contact persons make sure they understand the process before they start. Emphasize the importance of the evaluation and its impact on the whole institution.
- Reinforce to vendors that they may not "bribe" end users before or during the evaluation. We allowed candy bribes for returned evaluation forms only.

Type of Staff	Estimated Hours Spent on Butterfly Needle Evaluation - Phase 4
Management	20
Administrative	15
Front-line	50
Total	**85**

Other, non-labor costs
1. Xeroxing evaluation forms

Addendum # 1
EVALUATION FORM FOR SAFETY BUTTERFLY DEVICE

Your Name / Occupation / Title_____

Department / Unit_____

Today's Date_____

Which product are you evaluating?

□ Product A / description □ Product B /description

Approximately how many times did you use this device?
A) □ <10 times B) □ 10-20 times C) □ 21-30 times

D) □ 31-50 times E) □ >50 times

B) This device was used on the following patients (check all that apply)
□Adults □ Children □ Infants □ Neonates

C) This device was used in the following settings (check all that apply)
□ Inpatient general nursing unit □ ICU / critical care □ Operating room
□ Emergency Department □ Radiology □ Outpatient clinic
□ Laboratory □ Oncology
□ Specialty unit (e.g., Dialysis)_____
(Please specify)

	Product issues	**Circle One** **1 2 3 4 5 N/A** **Agree Disagree** **Yes No**
1.	The safety butterfly device can be used on fragile or small veins?	Yes No N/A
2.	If the answer to # 1 was no, please list the types of patients that the safety butterfly was NOT suitable for_____	
3.	This safety butterfly device eliminated /reduced the risk of sprays, blood leakage, and /or drips	1 2 3 4 5 N/A
4.	This device allowed you to see what you need to see during the blood draw	1 2 3 4 5 N/A
5.	The safety device is compatible with other devices it may have to connect to, or interact with (i.e., syringes, and blood collection devices)?	Yes No N/A
6.	If the answer to # 5 is "no", what devices was the safety product NOT compatible with? _____	
7.	Your training for this safety device was adequate	1 2 3 4 5 N/A
8.	You need extensive training to use this safety device	1 2 3 4 5 N/A

	Product issues	Circle One 1 Agree Yes	2	3	4	5 Disagree No	N/A
9.	You have to activate the safety feature of this product?	Yes				No	N/A
10.	If the answer to # 9 is yes, can the safety feature of this product be activated using one hand?	Yes				No	N/A
11.	The safety feature works reliably	1	2	3	4	5	N/A
12.	Both hands stay behind the needle or sharp when activating the safety feature	1	2	3	4	5	N/A
13.	The safety feature interferes with normal use of this product	1	2	3	4	5	N/A
14.	The device has an audible or visual indicator that the "safety" feature has been activated	1	2	3	4	5	N/A
15.	This safety device caused more pain to the patient than usual	1	2	3	4	5	N/A
16	The use of this device increased the number of sticks to the patient	1	2	3	4	5	N/A
17.	This product worked satisfactorily for my particular patient population	1	2	3	4	5	N/A
18.	The exposed sharp was blunted or covered once it was used	1	2	3	4	5	N/A
19.	Using this product required compulsory use of the safety feature	Yes				No	N/A
20.	The safety device is easy to store (packaging works well, does not take up too much space etc.)	1	2	3	4	5	N/A
21.	The package of the safety device is easy to open	1	2	3	4	5	N/A
22.	Is it easy to identify the size & type of safety product from the packaging	1	2	3	4	5	N/A
23.	Using this device instead of a conventional device will result in only a modest (if any) increase in sharps container waste volume (Answer "disagree" if the device will increase waste volume significantly)	1	2	3	4	5	N/A
24.	This safety device is easy to dispose of in the sharps waste container	1	2	3	4	5	N/A
25.	Approximately how many times did you use the safety device before you felt comfortable with it?	Never ☐	1time ☐	5 times ☐	10 times ☐	15 times ☐	20 times ☐
26.	Did you have any problems with this safety device? If "yes", please explain_____						Y N

THANK YOU FOR PARTICIPATING IN THIS PRODUCT EVALUATION
YOUR INPUT IS VALUABLE TO OUR ONGOING EFFORTS TO REDUCE BLOODBORNE EXPOSURES

Please return this form to the contact person for your unit or

Send to: Team Leader name/address

Addendum # 2
Sharps Injury Prevention Team
Safety Butterfly Needle Evaluation

Goals

To evaluate safety butterfly needles for implementation.
To reduce high-risk bloodborne pathogen exposures to employees.

Test Products

Two brands of safety butterfly needles will be tested:

Company Name	Product Name	Company Representative
Company A	Brand name A	Vendor name /Phone number Fax number /E-mail
Company B	Brand name B	Vendor name /Phone number Fax number /E-mail

Test Populations

The following areas have been selected to test the products. These areas represent common users of butterfly needles along with select patient populations:

Department / Area	Contact Person / Area Representative	Phone Number	Pager	Approximate Number to Trial
Laboratory Medicine - Phlebotomy Major users	Name	Phone number	Pager #	50
Neurosurgical Nursing Unit Moderate users	Name	Phone number	Pager #	50
Vascular Surgery & Medicine Nursing Unit Moderate users	Name	Phone number	Pager #	50
Internal Medicine Nursing Unit Moderate users	Name	Phone number	Pager #	50
Subacute Services Less frequent users	Name	Phone number	Pager #	25
Radiology CT/MRI Major users	Name	Phone number	Pager #	75

Department / Area	Contact Person / Area Representative	Phone Number	Pager	Approximate Number to Trial
Many patients with difficult veins (cancer patients)			#	
Emergency Department Major users	Name	Phone number	Pager #	75
Pediatrics All pediatric units Nurses - infrequent users Physicians - infrequent users Peds phlebotomy - frequent users Difficult veins	Name	Phone number	Pager #	100
Occupational Health Frequent users	Name	Phone number	Pager #	50
Cancer Center Frequent users - difficult veins	Name	Phone number	Pager #	50

Product Sizes
Standard 21G 3/4" and 23G 3/4" needle sizes to be tested in adult patients.
Standard 21G 3/4", 23G 3/4", and 25G 3/4" needles sizes to be tested in pediatric patients.

Evaluators
- Each area contact person should select 2-5 individuals to test the products.
- Persons testing the products should range in clinical skills, from highly skilled seasoned practitioners to newer, less skilled persons.
- If non-nursing personnel (i.e., physicians, respiratory therapists) use butterfly needles on your patient population be sure to include them as persons to test the products.

Evaluation Forms
All persons testing product **MUST COMPLETE A STANDARD EVALUATION FORM**. The evaluation form for butterfly needles is attached. Additional copies are available from:

Time frame
Evaluation will be conducted from February - March
Please evaluate the products one at a time

Products should be tested in the following order (product testing order was picked at random to eliminate bias as much as possible)

1. Brand A	Brand A name	February
2. Brand B	Brand B name	March

Process

1. The company representatives will arrange to meet with each area contact person to bring in the product and provide training to all individuals involved in the evaluation.
2. Contact person selects individuals to test product and ensures that each person receives training on product use.
3. Persons are given a select amount of product to test. (Note: Amounts listed per area are approximate. Each area may request more product if they feel it is necessary to adequately trial product.)
4. Each person completes the evaluation form **AFTER THEY HAVE USED THE ENTIRE AMOUNT OF THE PRODUCT GIVEN TO THEM.**
5. Evaluation forms are collected by the contact person and sent to: Name of team leader / address

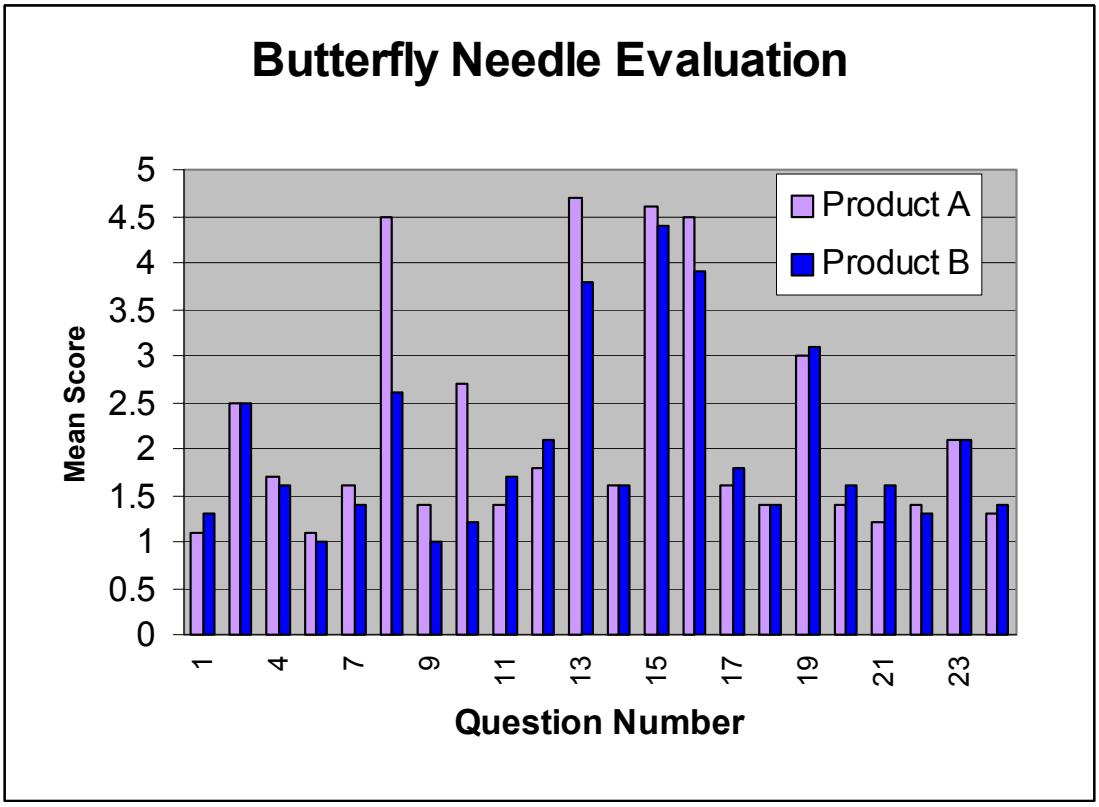
Thank you for your assistance with this product evaluation
Your efforts are valuable to our ongoing efforts to reduce bloodborne pathogen exposures

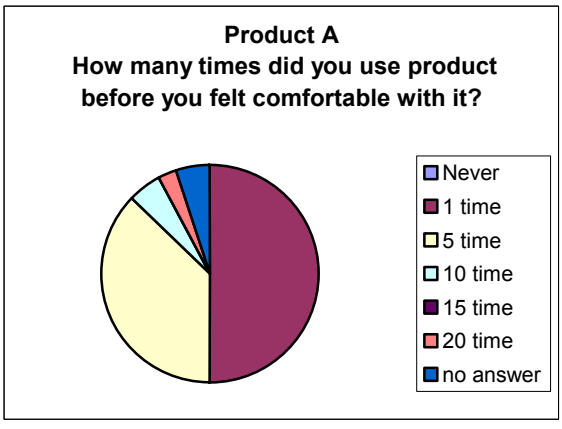
Any Questions?

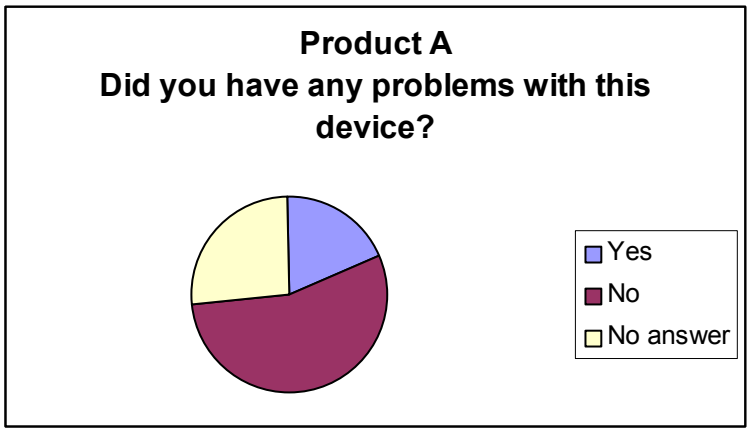
Call: Name of team leader

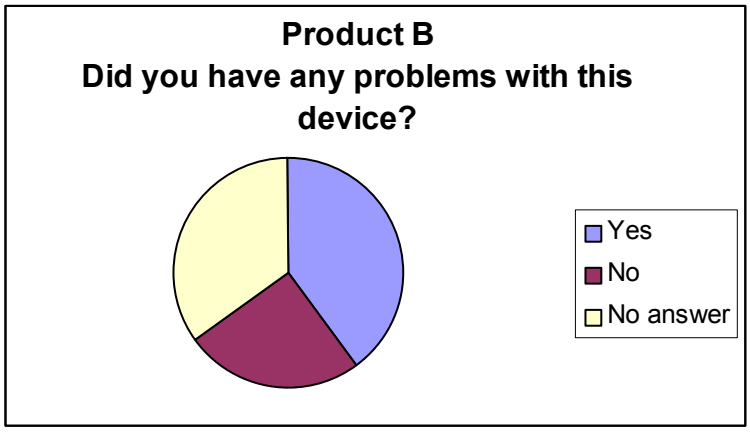
Addendum #3

Sample results









#	Question	Result (mean)	Desired score
1.	The safety butterfly device can be used on fragile or small veins?	**Product A 1.1** Product B 1.3	1.0
3.	This safety butterfly device eliminated /reduced the risk of sprays, blood leakage, and /or drips	Product A 2.5 Product B 2.5	1.0
4.	This device allowed you to see what you need to see during the blood draw	Product A 1.7 **Product B 1.6**	1.0
5.	The safety device is compatible with other devices it may have to connect to, or interact with (i.e., syringes, blood collection devices)?	Product A 1.1 **Product B 1.0**	1.0
7.	Your training for this safety device was adequate	Product A 1.6 **Product B 1.4**	1.0
8.	You need extensive training to use this safety device	**Product A 4.5** Product B 2.6	5.0

#	Question	Result (mean)	Desired score
9.	You have to activate the safety feature of this product?	**Product A 1.4** Product B 1.0	5.0
10.	If the answer to # 9 is yes, can the safety feature of this product be activated using one hand?	Product A 2.7 **Product B 1.2**	1.0
11.	The safety feature works reliably	**Product A 1.4** Product B 1.7	1.0
12.	Both hands stay behind the needle or sharp when activating the safety feature	**Product A 1.8** Product B 2.1	1.0
13.	The safety feature interferes with normal use of this product	**Product A 4.7** Product B 3.8	5.0
14.	The device has an audible or visual indicator that the "safety" feature has been activated	Product A 1.6 Product B 1.6	1.0
15.	This safety device caused more pain to the patient than usual	**Product A 4.6** Product B 4.4	5.0
16	The use of this device increased the number of sticks to the patient	**Product A 4.5** Product B 3.9	5.0
17.	This product worked satisfactorily for my particular patient population	**Product A 1.6** Product B 1.8	1.0
18.	The exposed sharp was blunted or covered once it was used	Product A 1.4 Product B 1.4	1.0
19.	Using this product required compulsory use of the safety feature	**Product A 3.0** Product B 3.1	1.0
20.	The safety device is easy to store (packaging works well, does not take up too much space etc.)	**Product A 1.4** Product B 1.6	1.0
21.	The package of the safety device is easy to open	**Product A 1.2** Product B 1.6	1.0
22.	Is it easy to identify the size & type of safety product from the packaging	Product A 1.4 **Product B 1.3**	1.0
23.	Using this device instead of a conventional device will result in only a modest (if any) increase in sharps container waste volume (Answer "disagree" if the device will increase waste volume significantly)	Product A 2.1 Product B 2.1	1.0
24.	This safety device is easy to dispose of in the sharps waste container	**Product A 1.3** Product B 1.4	1.0